

"Mrs. R. S. Marshall"; letter dated "April 29, 1954" signed "Jean Steck P. O. Box 548, Prineville, Ore." letter undated signed "Robert Warmbier Clifton, Illinois," and letter undated signed "Maurice Warmbier Clifton, Illinois."

LIBELED: 1-14-55, W. Dist. Wis.

CHARGE: 502 (a)—the labeling accompanying the article while held for sale contained false and misleading representations that the article provided an adequate and effective treatment for arthritis, "other chronic diseases," multiple sclerosis, bursitis, and deafness; and, 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use in the treatment of the diseases and conditions for which it was intended, namely, arthritis, "other chronic diseases," multiple sclerosis, bursitis, and deafness.

DISPOSITION: Victor H. Baker, Lone Rock, Wis., the owner of the article, appeared as claimant and filed an answer admitting that the article was transported unlabeled in interstate commerce but denying that the article was misbranded as alleged in the libel. Thereafter, a motion for summary judgment was filed by the Government and was granted by the court on 6-24-55, on the ground that there was no genuine issue as to any material fact. On the same day, the court entered a judgment of forfeiture and ordered that the article be destroyed.

4667. Various devices. (Inj. No. 257.)

COMPLAINT FILED: 10-2-53, N. Dist. Calif., against Electronic Medical Foundation, a corporation, San Francisco, Calif., formerly known as the College of Electronic Medicine, and against Fred J. Hart, Salinas, Calif., president of the corporation and in full charge of its operations, Dr. Thomas Colson, San Francisco, Calif., secretary-treasurer of the corporation and in charge of the corporation's diagnostic laboratory and electronic research division, and Dr. Charles J. Pflueger, Los Angeles, Calif., a member of the corporation's board of trustees and executive committee.

NATURE OF BUSINESS: The complaint alleged that the defendants were actively promoting the distribution in interstate commerce of certain devices, namely, *Oscilloclast*, *Oscillotron*, *Regular Push Button Shortwave Oscilloclast*, *Sweep Oscillotron*, *Sinusoidal Four-in-One Shortwave Oscillotron*, *Galvanic Five-in-One Shortwave Oscillotron*, all of which are hereinafter referred to as the *Oscilloclast* and *Oscillotron* type of device; *Depolaray*, *Depolatron*, *Depolaray Chair*, *Depolatron Chair*, *Depolaray Junior*, *Electropad*, *New Depolaray Junior*, all of which are hereinafter referred to as the *Dipolaray* and *Depolatron* type of device; and other similar "therapeutic" devices, as well as certain devices designated as *Blood Specimen Carriers* and intended for use as component parts of a "diagnostic" device designated as the *Radioscope*; that, during the past 30 years, the defendants had been promoting the sale and distribution of the devices by such means as lectures, testimonials, case reports, leaflets, books and periodicals, all purporting to have a scientific basis; that the defendants' interstate promotional activities were divided into two major parts, namely, the sale of their "diagnostic" service and the distribution of their "therapeutic" devices; that the defendants maintained their "diagnostic" device, called a *Radioscope*, at their San Francisco office where practitioners who purchased or used defendants' "therapeutic" devices would have access to defendants' "diagnostic" service; that, for a fee, the defendants would accept and examine blood specimens taken from patients of such prac-

tioners and then furnish the practitioners with the "diagnostic" data allegedly obtained through the use of the *Radioscope*; and, that upon the basis of such "diagnostic" data, the practitioners would treat their patients by using the "therapeutic" devices previously obtained from the defendants.

NATURE OF DEVICES: The *Radioscope* was represented as a "tuning apparatus" by which defendants asserted it was possible to distinguish the allegedly characteristic radio frequencies associated with different diseases. The *Radioscope* was a box containing dials, lights, and wires, and a slot in which would be placed a *Specimen Carrier* of filter paper bearing dried blood of a patient. When the *Radioscope* was used to "diagnose" disease, metal plates that were connected to the box were held by a person who was designated as the "reagent" and who was supposed to serve as a detector for the presence of radiations allegedly emanating from the dried blood in the *Specimen Carrier*. The "reagent's" part was passive. The operator would stroke the abdomen of the "reagent" with a plastic wand and determine whether or not the wand would "stick" on a particular spot on the abdomen. If the wand did "stick," that was supposed to be a manifestation of an "electronic reaction," and the operator allegedly could determine thereby whether the "electronic reaction" was one of health or disease, and if the "reaction" was one of disease, he allegedly could further determine its intensity, kind, location, and significance. The "reactions" which the operator allegedly elicited with the wand were supposed to vary according to whatever disease may be present in the person from whom that blood sample was taken, even though that person may be anywhere in the world. The ability of the blood sample to emanate these so-called radiations allegedly would last several weeks from the time the blood originally was drawn and allegedly registered the condition of the patient as of the time it was drawn. The sample allegedly reflected the presence of disease in any part of the body.

The "reactions" obtained from a blood specimen through a *Radioscope* examination were allegedly used for diagnosing the patient's condition. Such diagnostic data were recorded by defendants on a sheet entitled "Electronic Blood Chemistry Report," and interpreted by defendants on a sheet identified as "Dial Settings and Indicated Toxins." After filling out such sheets, defendants would send them together with recommendations for treatment to the practitioner who had submitted the blood specimen and who used this data as a basis for treating his patient with "therapeutic" devices obtained from the defendants.

The therapeutic qualities of defendants' devices (in their various models and combinations) were alleged to rest upon the representation that such devices produced certain low power radio waves and low frequency alternating magnetic energy which, when applied to the body, would "normalize" disease tissue thereby correcting disease conditions.

ACCOMPANYING LABELING: Literature entitled "Extension Bulletin No. 7," "Depolatherm, Depolatron, Depolaray Procedure," "Electronic Medical Digest—Summer 1950," "Shortwave Oscilloclast Oscillotron," "Extension Bulletin No. 6," "Improved Experimental Oscillotron Instructions," "Electronic Medical Digest—May-June, 1947" (This item was incorporated by reference in "Electronic Medical Digest—Summer 1950"), "Dial Settings and Indicated Toxins," "Suggested Shortwave Oscilloclast Treatment," "Information Sheet," "Electronic Blood Chemistry Report," and certain envelopes bearing statements relating to the *Blood Specimen Carriers*.

CHARGE: The complaint alleged that the *Depolaray* and *Depolatron type of device* and the *Oscilloclast* and *Oscillotron type of device* were misbranded under 502 (a) as follows:

1. The labeling of each such device created the false and misleading impression that the device was an outstanding therapeutic agent valuable in all kinds of disease conditions and was especially beneficial in the treatment of certain named disease conditions and abnormalities as follows:

(a) (*Depolaray* and *Depolatron type of device*) Abdominal pain, abscess on side of anus, abscessed teeth, arthritis of both knees, backaches, back sprains, baseball shoulders, Bell's palsy, black widow spider bite, bladder inflammation, boils, bronchitis, bruises (on various parts of body), bursitis, cancer of skin, carbuncles (including large carbuncle on back of neck), charley horse, colds, constipation, chronic cholecystitis, cystitis, ear trouble, eczema, eustachian tube infection, exhaustion, frequency of urination, fullness in perineum, gall bladder congestion, gallbladder irritation, gastric ulcers, gonad disease, hemorrhoids (including bleeding hemorrhoids) herpes zoster, high blood pressure, hip pointers, hornet stings, hyperthyroidism, hypertrophic (or inflamed) prostate, indigestion, inflammatory rheumatism, influenza (including intestinal "flu"), inguinal hernia, iritis, irritation of throat, loose coccyx, mastoiditis, maxillary sinus infection, middle ear infection, muscular rheumatism, neurasthenia, ovarian disorders, ovaritis, pain in eye, rectum, shoulder, or any part of body, phlebitis complicating varicose veins, poor elimination, pressure over coccyx, prostatic congestion, pulled muscle, septic sore throat, severe pain and swelling of right hip and thigh, shin splints, shingles, sinus infection, sore elbows, sore throat, sprained elbow, stiff ankle, stone bruise, swelling of head and face, tackle shoulder, tonsillitis, thrombosis of hemorrhoid, toxic condition, tumor of neck (and other tumors on other parts of body), ulcers (small), varicose ulcers, and varicose veins.

(b) (*Oscilloclast* and *Oscillotron type of device*) Abdominal distention due to gas, abdominal pressure, absence of secondary sex development, primary amenorrhea, anemia, angina pectoris, ankle swelling, anterior poliomyelitis, aphonia, appendix area tenderness, arrhythmia of heart, arthritis both shoulders, asthenia, asthma, bilateral auditory nerve degeneration, backache (including lumbar backache), back pain, bleeding gums, blotches on shoulder, breast tumors, cancer (including cancer of breast and stomach), cataract, cervix inflamed, cholecystitis, cholelithiasis, chorea, colds (including frequent and repeated colds), complexion sallow, confusion, constipation, spasmodic contraction of hands, coronary thrombosis, cough (including constant cough), cramps in lumbar region, deafness (including increasing deafness both ears), despondency, difficulty in breathing, discharge from vagina, discouraged condition, dizziness, double vision, easy fatigability, eczema (including that covering large body areas and of many years duration), enlarged and inflamed tonsils, enlarged prostate, epigastric and gallbladder region pain, extreme weakness, fatigue (including undue fatigue), feet purple, frequent urination, severe frontal headaches, gas on stomach after every meal, gastric ulcer or cancer, general skin ailments, glandular nodules swollen in both groins, gums sore, headaches (including migraine, daily, frontal, and headaches with vomiting), hemiplegia (including hemiplegia with muscle rigidity), high blood pressure, inability to take food or to work due to nausea, inability to walk due to infantile paralysis, indigestion, infantile paralysis, inflammation (in-

cluding inflammation of gallbladder, ovary, kidneys, bladder, and other parts of body), insomnia, irritability, kidney colic, lassitude, liver area pain, loss of weight (including continued loss of weight), mental exhaustion, muddy complexion, multiple neuritis, nausea and vomiting (including frequent and continued nausea and vomiting), nervous breakdown (including frequent and repeated nervous breakdowns), general nervous exhaustion, nervousness, neuritis in head, neck, shoulders, and arms, night sweats, pain (including severe pain and nocturnal pain) in various parts of body (such as eyes, jaws, spine, teeth, over right kidney, mediastinal area, joints of right hand, etc.), paralysis both legs, pleurisy with effusion, poor vision, pressure in back of head, rales over both lungs, rapid heart, restless sleep, retarded reflexes, rheumatism of various parts of body (including shoulders and legs), rigid spinal muscles, sensory disturbances, sinus infections and other sinus conditions, sore throat, spastic neuritis including muscle spasms, spastic paralysis since birth, staggering gait, stiffening of joints, stomach pain, stumbling gait, swollen lower legs, tachycardia, temperature elevated, thyroid gland enlargement, tiring easily and all the time, toenails loose, toenails missing, tuberculosis (including tuberculosis of both lungs verified by X-ray and tuberculin test), tumors (including fatty tumors), ulcers of leg (down to bone with heavy drainage), underweight, unnaturally thin condition, upset stomach accompanied by headache, uterine tumor, vomiting (including vomiting immediately after eating and periodic vomiting), weakness, uric acid, pyorrhea, X-ray burn, menopause, pain, amebiasis, typhus, radium burn, actinomycosis, influenza, common cold in fallopian tube, in bone, in pancreas, in brain, in nerve ending, in skin, in eye, in colon, in uterus, in breast, in liver, and in ovary, exostosis, inflammation, nicotine, hay fever, bovine TB, human TB in heart, in thyroid, in cervix, in stomach, in appendix, in ethmoid, in bladder, in tooth, in anthrum [sic], in eye, in tonsil, in breast, in ear, in uterus, in esophagus, in salivary gland, in intestine, in bone, in liver, in pancreas, in gallbladder, in skin, in kidney, in rectum, in ovary, in testicle, in prostate, in nerve ending, in brain, in frontal sinus, in lung, in lymph tissue, and in blood vessel, colicsepsis, arthritis, pinworm, diphtheria, fatty tumor, carcinosis in spleen, in pancreas, in gallbladder, in liver, in nerve, in esophagus, in skin, in uterus, in thyroid, in stomach, in gum, in blood vessel, in intestine, in prostate, in kidney, in breast, in ovary, in lung, and in bone, urethral carbuncle, variola, neisserian [sic] in kidney, catarrh, eczema, necrosis, lues in leg sore, in stomach, and in prostate, gastric inflammation, lung congestion, general toxins, chondroma, connective tissue scar in bone, in soft tissue, in lung, and in adhesion, sarcosis in gallbladder, in liver, in prostate, in uterus, in ovary, in skin, in bone, in heart, in lymph, in breast, in intestine, in bone marrow, in stomach, in spleen, in brain, and in pancreas, ovarian cyst, Bang's disease, undulant fever, malta fever, streptotoxemia in colon, in pancreas, and in tooth, malaria, free pus, encapsulated pus, staphylotoxemia in eye, in tooth, in uterus, in tonsil, and in ovary, rhus toxicodendron, psora, fibroma, scarlatina, renal stones, chilblains, chickenpox, Rocky Mountain fever, malignancy, typhoid, impetigo, fermentation, putrefaction, adhesions, scar tissue, tropical ulcer, chancroid, rabies, mumps, hay fever, meningococcus, pellagra, fibroid, epilepsy, general toxemia, granuloma, warts, pain (inflammatory), anthrax, arteriosclerosis, autointoxication, bone exostosis, goiter, measles, migraine, general toxins fermentation, angioneurotic edema, carcinoma, epithelioma, acute inflammation, pneumococcemia, and pneumonia.

2. The labeling of the *Oscilloclast* and *Oscillotron* type of device was false and misleading—

(a) In that the labeling represented and suggested that each such device in their various models were essentially alike and that the benefits allegedly obtained from one such model may reasonably be expected to be obtained from the others; and such labeling failed to reveal the following facts which were material in the light of such representations and suggestions:

(i) That some of the models were specifically designed to eliminate the presence of high frequency energy from the treatment face of the depolarizing electrodes, while other models were specifically designed to create and apply high frequency energy on the treatment face of the depolarizing electrodes.

(ii) That some of the models were specifically designed to give a depolarizer electrode output which was continuous in nature, while other models were designed to give a depolarizer electrode output which was pulsed in nature.

(iii) That "case reports" used in the current promotion of all of such models without differentiation were derived from the various models employing different characteristic electrical outputs and contradictory theories.

(iv) That the basic circuits of the various models were fundamentally different.

(b) In that the labeling represented and suggested that the so-called "Knight Circuit," as used in some models of the *Oscilloclast* and *Oscillotron* and not in others, enhanced the therapeutic value of such devices; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That the "Knight Circuit" as used in the devices was simply a switch which continually turned on and off the electrical current coming into the devices, thereby creating electrical sparks that were common to all man-made mechanical or motor-driven switches.

(c) In that the labeling of each such device represented and suggested that various models of the *Oscilloclast* and *Oscillotron* derived their alleged therapeutic qualities from the generation and application of weak, interrupted radio waves ranging in frequency between 43.000 megacycles and 43.357 megacycles; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That the atmosphere was continually carrying to and through the body of every human being interrupted radio waves of the same frequency range and order of magnitude generated by radio stations, mobile telephone units, etc.

(d) In that the labeling of each such device represented and suggested that the presence of a Tesla coil in the circuit was indispensable to the effective use of the *Oscilloclast* and *Oscillotron*; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That some models of the devices did not have a Tesla coil in their circuits.

(e) In that the labeling represented and suggested that the shortwave energy generated by the *Oscilloclast* and *Oscillotron* was transmitted to the patient through a wire and electrodes (flat-plate or mesh or those designed to be inserted into body orifices) placed on or in certain areas of the body; and such labeling failed to reveal the following fact, which was material in the light of such representations and suggestions:

(i) That most of such shortwave energy was dissipated into the atmosphere and did not reach the body through such wire and electrodes.

The complaint alleged also:

1. That the *Depolaray* and *Depolatron type of device*, the *Oscilloclast* and *Oscillotron type of device*, and the *Blood Specimen Carriers* were misbranded under 502 (a) as follows:

(a) In that the labeling of each such device was false and misleading since it represented and suggested:

(i) That another device, the *Radioscope*, was capable of being effectively used to diagnose disease, whereas the *Radioscope* was not capable of being effectively used for such purposes.

(ii) That it would enable the doctor to know "just what is happening or is about to happen to body tissue," the cause of a particular disease, "to what extent the tissue is affected thus eliminating the need for exploratory surgical operations," and recommended a method of effective treatment, whereas the *Radioscope* was not capable of being effectively used for such purposes.

(iii) That it could detect diseases in the body even before symptoms of the disease appeared, making it possible to treat a condition such as tuberculosis or cancer, "before it has a fighting chance to wreak havoc in body tissue," whereas the *Radioscope* was not capable of being effectively used for such purposes.

(b) In that the labeling of each such device made the following false and misleading representations and suggestions:

(i) That the *Oscilloclast* and *Oscillotron type of device* produced these constant radio frequency outputs under the suggested conditions of use: Button 0=43.000 megacycles, Button 1=43.245 megacycles, Button 2=43.296 megacycles, Button 3=43.322 megacycles, Button 4=43.338 megacycles, Button 5=43.346 megacycles, Button 6=43.350 megacycles, Button 7=43.352 megacycles, Button 8=43.354 megacycles, Button 9=43.356 megacycles, and Button 10=43.357 megacycles.

(ii) That the *Oscillotron* energy pulsed approximately 110 times per minute.

(iii) That the *Galvanic Five-in-One Shortwave Oscillotron* may be used as a sinusoidal instrument.

(iv) That there was no shock hazard in the use of the *Galvanic Five-in-One Shortwave Oscillotron*.

(v) That in operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the volume range of current to the patient was from 0 to 15 milliamperes current, and the voltage range was 0 to 110 volts, direct current.

(vi) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the 0-5-X-3 shunt increased the current three times.

(vii) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the use of the rate sweep provided a treatment of 11 different rates per minute with $5\frac{1}{2}$ seconds per minute devoted to each rate.

(viii) That the *Galvanic Five-in-One Shortwave Oscillotron* had a knob which controlled the phone jack receptacle marked "Pulse" in the lower right hand corner of the panel.

(ix) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, the operator could increase the flow of treating energy through a given lesion by placing one flat-plate electrode connected with the treating jack on one side of the lesion and another flat-plate electrode connected with the return jack on the opposite side of the lesion.

(x) That in the operation of the *Galvanic Five-in-One Shortwave Oscillotron*, there was a simultaneous pulsing of the current in the depolarizer electrodes and in the shortwave flat plates which permitted the body cells undergoing treatment to rest 90 times per minute.

(xi) That the depolarizer electrodes of the *Galvanic Five-in-One Shortwave Oscillotron* produced a magnetic field of 80 gaussess strength at their treating side.

(xii) That the low frequency electromagnetic energy output of the *Electropad* and the *Depolaray Junior* was 40 percent and 25 percent, respectively, of the energy output of the *Depolaray*.

(xiii) That the pulsing mechanism in the *Depolatherm Four-in-One*, also known as *Pulsating Infrared Depolatherm*, produced a change of voltage that created a wider range of infrared frequencies and a more effective instrument.

(c) In that the labeling of the *Blood Specimen Carriers* was false and misleading since it represented and suggested that such devices were capable of being used to carry disease radiations from a specimen of dried blood, which radiations allegedly could serve as an indication of the intensity, kind, location, and significance of any disease conditions present in the body from which the blood was taken, whereas such devices were not capable of being effectively used for such purposes.

2. That each device was misbranded under 502 (f) (1) in that its labeling failed to bear adequate directions for use; and,

3. That each device was adulterated under 501 (c) in that its strength differed from, and its quality fell below, that which it purported and was represented to possess.

DISPOSITION: On 3-15-54, the court, with the consent of the government and the defendants, entered the following decree:

ROCHE, *District Judge*: "Plaintiff having filed a Complaint for Injunction in the above-entitled cause to restrain the defendants from further alleged violations of the Federal Food, Drug, and Cosmetic Act; and defendants having filed an Answer; and upon the consent of plaintiff and defendants before trial on the merits;

"IT IS HEREBY ORDERED, ADJUDGED, and DECREED that the defendants, Electronic Medical Foundation, Fred J. Hart, Thomas Colson, and Charles J. Pflueger, and each and all of their officers, agents, servants, employees, and all persons in active concert or participation with any of them, be and they are hereby enjoined and restrained during the pendency of this

action and until the final determination thereof, from doing any of the following acts, directly or indirectly, in violation of Sections 301 (a) or 301 (k) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 331 (a) or (k)) with respect to any of the articles of device hereinafter enumerated—namely, the Oscilloclast, Oscillotron, Regular Push Button Shortwave Oscilloclast, Sweep Oscillotron, Sinusoidal Four-in-One Shortwave Oscillotron, Galvanic Five-in-One Shortwave Oscillotron, Depolaray, Depolatron, Depolaray Chair, Depolatron Chair, Depolaray Junior, Electropad, New Depolaray Junior, and Blood Specimen Carriers—or any similar article of device allegedly capable of transporting blood for diagnosis by the Radioscope or of producing or measuring low power radio waves or electromagnetic energy or low frequency alternating magnetic energy, or any accessory, component, or part of any such article:

“(1) Introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce any such article of device which is:

(a) Misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any representation or suggestion in its labeling which conveys the impression that such article, or any of the other articles enumerated above, including the Radioscope, has value in the treatment or diagnosis of any kind of disease condition or has value in affecting any structure or function of the body of man or other animals; or

(b) Misbranded within the meaning of Section 502 (a) of the Act (21 U. S. C. 352 (a)) by reason of any other false or misleading representation or suggestion in its labeling; or

(c) Misbranded within the meaning of Section 502 (f) (1) of the Act (21 U. S. C. 352 (f) (1)) in that its labeling does not bear adequate directions for use because it does not contain a statement of all the purposes and conditions for which the articles are intended by the defendants; or

(d) Adulterated within the meaning of Section 501 (c) of the Act (21 U. S. C. 351 (c)) in that (1) its strength differs from or its quality falls below that which it purports or is represented to possess, or (2) it purports to produce or measure low power radio waves or electromagnetic energy or low frequency alternating magnetic energy which, when applied to the body, “normalize” disease tissue thereby correcting disease conditions, or (3) it purports to have diagnostic or therapeutic qualities; or

“(2) Doing any act or causing any act to be done with respect to any such article while such article is held for sale after shipment in interstate commerce which results in said article becoming misbranded or adulterated in any of the aforesaid respects; and

“IT IS FURTHER ORDERED that this injunction shall remain in effect until final disposition of this cause by this Court after trial on the merits; and

“IT IS FURTHER ORDERED that any trial on the merits shall be preceded by at least 90 days’ notice to all parties with opportunity for utilizing the discovery and pre-trial procedure; and

“IT IS FURTHER ORDERED that at any such trial on the merits defendants’ consent to this Decree shall not be deemed an admission against them, provided, however, that this Decree may be the basis for Contempt proceedings for any violation thereof; and

“IT IS FURTHER ORDERED that this Court expressly retain jurisdiction over the subject matter and parties herein in order that it may issue such further Orders and Decrees as may be necessary to the proper disposition of this proceeding.”

4668. Voluptae device. (Inj. No. 288.)

COMPLAINT FOR INJUNCTION FILED: 3-11-55, S. Dist. Calif., against Hollywood Models, Inc., doing business under the fictitious name of Voluptae at Los Angeles, Calif., and against Lois Schwartz, also known as Anne Harris, president of the corporation.

CHARGE: The complaint alleged that the defendants were the interstate promoters and distributors of the device designated by the name of *Voluptae*,